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Date of certificate : 2022 - 12 - 08

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Product description

Corning Octagonal PET Bottle, 125mL Graduated, 31mm IATA-Validated Screw Cap Sterile, Pre-assembled, 24/Tray, 48/Case

Catalogue number

432331

Manufacturing date

2022/11/01

Lot number

838168

Quality Management System : Complies with the current version of the ISO9001 standard

Raw material statement

The Substances Bisphenol A, BSE / TSE, latex, and phthalates are not used or intentionally incorporated in the manufacture of the raw materials or final product.

Sterility Assurance Level

This product is sterilized using an irradiation method compliant with the requirements of ANSI/AAMI/ISO 11137 to achieve a Sterility Assurance Level (SAL) of 10⁻⁶

Leakproof - With a torque value of 2,5N.m (22lb.in), this product meets IATA Packaging Instruction 650 requirements to ensure leakproof performance during air transport conditions; however, this is not designed for packaging and transport of UN3373 Biological and Infectious Substances.

Non-Pyrogenic - Tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85> "Bacterial Endotoxins Test." The acceptance level for product is less than 0.1 EU/ml.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the standards USP Class VI Chapter <87>, "Biological reactivity Tests, in Vitro" and Chapter <88>, "Biological Reactivity Tests, in Vivo."

Expiration date

2025/11/01

Expiration statement

This product is designed to have an expiration date of 3 years from the date of manufacture regarding sterility.

Performance testing (AQL)

Inspection based on a statistically significant number of samples towards to internal or agreed specifications that determine Assurance Quality Level. We confirm that product is compliant with ISO993/USP31 : Non-cytotoxic, Endotoxin-free / non-pyrogenic.

This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release



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